

**IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF MISSOURI
ST. LOUIS DIVISION**

<p>UNITED STATES OF AMERICA, ex rel. [UNDER SEAL],</p> <p style="text-align: center;">Plaintiff</p> <p>vs.</p> <p>[UNDER SEAL],</p> <p style="text-align: center;">Defendants</p>	§ § § § § § § § § § §	<p>CIVIL ACTION NO.</p> <p style="font-size: 24pt; font-weight: bold;">4:05CV00650</p> <p><u>UNDER SEAL</u></p>
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PLAINTIFFS' COMPLAINT UNDER 31 U.S.C. § 3730

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II.

The parties

2. Plaintiff, **PAUL MONTGOMERY ("Montgomery")**, is an individual residing in the State of Arkansas.

3. Plaintiff, **LONNIE E. HARRISON, M.D. ("Harrison")**, is an individual residing in the State of Arkansas.

4. Defendant, **SISTERS OF MERCY HEALTH SYSTEM ("Mercy System")**, is a non-profit corporation with its principal place of business at 14528 S. Outer Forty, Suite 100, Chesterfield, MO, 63017. Its registered agent for service or process, Bernard A. Duco, Jr., can be served at its registered office, 14528 S. Outer Forty, Suite 100, Chesterfield, MO, 63017.

5. Defendant, **ST. EDWARD MERCY MEDICAL CENTER ("St. Edward")**, is a non-profit corporation with its principal place of business at 7301 Rogers Avenue, Fort Smith, AR, 72901. Its registered agent for service or process, Eileen Kradel, can be served at its registered office, 7301 Rogers Avenue, Fort Smith, AR, 72901.

6. Defendant, **COOPER CLINIC, P.A. ("Cooper Clinic")**, is a professional association with its principal place of business at 7001 Rogers Avenue, Fort Smith, AR, 72903. Its registered agent for service of process, R. P. Jack Davidson, M.D., can be served at its registered office, 6801 Rogers Avenue, Fort Smith, AR, 72903.

7. Defendant, **D. MARK McCOY, M.D. ("McCoy")**, is an individual residing in the State of Arkansas and he can be served at 1500 Dodson Avenue, Sparks Medical Plaza, Fort Smith, AR, 72901.

8. Defendant, **TIMOTHY C. WAACK, M.D. ("Waack")**, is an individual residing in the State of Arkansas and he can be served at 7001 Rogers Avenue, Fort Smith, AR, 72903.

9. Defendant, **RILEY D. FOREMAN, D.O. ("Foreman")**, is an individual residing in the State of Arkansas and he can be served at 7001 Rogers Avenue, Fort Smith, AR, 72903.

10. Defendant, **SPARKS HEALTH SYSTEM ("Sparks System")**, is an Arkansas non-profit corporation with its principal place of business at 1311 South I Street, Fort Smith, AR, 72901. Its registered agent for service or process, John A. Guest, can be served at its registered office, 1311 South I Street, Fort Smith, AR, 72901.

11. Defendant, **SPARKS REGIONAL MEDICAL CENTER OF FORT SMITH, LLC ("Sparks")**, is a Delaware limited liability company with its principal place of business at 1311 South I Street, Fort Smith, AR, 72901. Its registered agent for service or process, the Corporation Service Company, can be served at its registered office, 120 East Fourth Street, Little Rock, AR, 72201.

12. Defendant, **WESTERN ARKANSAS HEART, LUNG AND VASCULAR SURGICAL ASSOCIATES, P.A. ("Western Associates")**, is an Arkansas professional association with its principal place of business at 1500 Dodson Avenue, Fort Smith, AR, 72901. Its registered agent for service or process, Robert Jaggers, can be served at its registered office, 1500 Dodson Avenue, Fort Smith, AR, 72901.

III.

Filing under seal

13. In accordance with 31 U.S.C. § 3730(b)(2), this complaint is filed in camera and will remain under seal and will not be served on the defendants until the Court so orders. Copies of the complaint and a written disclosure of substantially all material evidence and information the Plaintiffs possess have been served contemporaneously herewith on the United States pursuant to 31 U.S.C. § 3730(b)(2) and Fed.R.Civ.P. 4(i).

IV.

Jurisdiction and venue

14. This Court has jurisdiction of this action under 28 U.S.C. §§ 1331 and 1345 and 31 U.S.C. §§ 3730 and 3732. The action arises out of violations of 31 U.S.C. § 3729 by the defendants, and one or more of the defendants can be found, resides or transacts business in this judicial district, within the meaning of 31 U.S.C. § 3732(a).

15. Venue is proper in this judicial district pursuant to 28 U.S.C. §§ 1391 and 1395.

V.

Plaintiffs' direct and independent knowledge of defendants' fraudulent conduct and voluntary disclosure of the information to the government before filing this action

16. Plaintiff Montgomery gained direct and independent knowledge of the Defendants' fraudulent submission of claims to federal health care programs for medically unnecessary cardiac and vascular surgical and interventional procedures in his capacity as a patient of St. Edward and Cooper Clinic physicians McCoy, Waack and Foreman. Montgomery underwent medically unnecessary coronary artery bypass surgery in June, 1998 and medically unnecessary bypass surgery on his legs in August, 1998. Due to complications resulting from the initial medically unnecessary bypass procedures performed on his legs, Montgomery underwent several subsequent surgical procedures culminating in the amputation of his right leg.

17. Plaintiff Harrison gained direct and independent knowledge of the Defendants' fraudulent submission of claims to federal health care programs for medically unnecessary surgical procedures, and for medical services that were not provided, in his capacity as a practicing cardiologist at St. Edward from 1994 to 2000.

18. Before filing this action, Plaintiffs personally and/or through counsel voluntarily provided all their material evidence and information of the Defendants' fraudulent practices and false claims to law

enforcement offices, officials and agencies responsible for the oversight and enforcement of the claims in question, including Assistant United States' Attorneys with the United States Attorney's Office for the Eastern District of Missouri, and special agents of the Federal Bureau of Investigation and the U.S. Department of Health and Human Services, Office of Inspector General.

19. Each Plaintiff is an "original source" of his information within the meaning of 31 U.S.C. § 3730(e)(4)(A) and (B).

VI.

Party information

20. Relator Montgomery is a former Fort Smith law enforcement officer and was also a heavy equipment salesman. As a result of medically unnecessary bypass surgeries performed by McCoy at St. Edwards, Montgomery underwent the amputation of his right leg and is now predisposed to a greater risk of premature closure of his heart vessels, heart attack and death.

21. Relator Harrison from 1994 to 2000 practiced as a cardiologist at St. Edward, where he worked with McCoy, Waack and Foreman. He treated Montgomery subsequent to the medically unnecessary operations performed on Montgomery by McCoy.

22. Defendant Mercy System was incorporated in the State of Missouri on or about September 30, 1986. Under the organizational umbrella of Mercy System, there are nine subsidiary health systems or networks. One of the nine is the St. Edward Mercy Health Network, which includes St. Edward.

23. St. Edward was incorporated in the State of Arkansas on or about April 25, 1973. St. Edward is a member of the St. Edward Mercy Health Network, which is a subsidiary of Mercy System. St. Edward is closely affiliated with Cooper Clinic and grants practice privileges to all of Cooper's physicians. Defendants Waack and Foreman were members of Cooper at all times relevant to this

Complaint. McCoy was a member of Cooper from approximately 1993 to May, 2000.

24. Defendant Cooper Clinic was incorporated in the State of Arkansas on or about September 27, 1973. Cooper Clinic is a physician practice group that is closely affiliated with St. Edward. All physician members of Cooper Clinic have privileges and practice primarily, if not exclusively, at St. Edward. Cooper Clinic is located next door to the St. Edward Centers for Excellence which houses the St. Edward Mercy Heart Center, as well as St Edward Outpatient Center, St. Edward Women's Center and Hembree Mercy Cancer Center. Cooper Clinic physicians filled the majority of the positions on the peer review committees at St. Edward, including the committee that reviewed mortality and morbidity cases and statistics concerning coronary surgeries and angioplasties.

25. Sparks System is an Arkansas non-profit corporation formed on or about August 3, 2000. The Sparks System is comprised of the wholly owned subsidiaries Sparks Regional Medical Center of Fort Smith; the Sparks Medical Foundation, which is comprised of more than 83 Sparks employed physicians in 35 clinics in the greater Fort Smith area; the Sparks Foundation, which provides financial support to the Sparks System; and Sparks PremierCare, a provider managed Medicare HMO.

26. Sparks is a Delaware limited liability corporation established on or about July 1, 2004 and wholly owned by Sparks System. Sparks is staffed by Sparks Medical Foundation physicians. In 1984, Sparks founded Arkansas's first heart institute, the Stanley E. Evans Heart Institute.

27. Western Associates was incorporated in the State of Arkansas on or about March 1, 2001. Western is an independent physician practice group in Fort Smith, Arkansas whose physicians have practice privileges at Sparks and at St. Edward. McCoy has been a member of Western Associates since 2001.

28. McCoy joined Cooper Clinic in 1993 and established Cooper Clinic's Cardiothoracic surgery department at that time. McCoy is a surgeon specializing in thoracic, cardiac, endovascular and

peripheral vascular surgery. McCoy was a member of Cooper Clinic until May, 2000. After a one year absence from the state, he returned to Ft. Smith, joined Western Associates in 2001, and began performing his surgeries at Sparks.

29. Waack is a cardiologist in Fort Smith, Arkansas. Waack joined Cooper Clinic in 1990 as a staff physician in the Department of Cardiology and has served at times as the Chair of the **Coronary Artery Bypass Grafting (aka CABG/Specials)** peer review committee at St. Edward.

30. Foreman joined the cardiology department of Cooper Clinic in 1996.

VII.

Preliminary statement of defendants' fraudulent conduct

31. Many of the surgical and interventional procedures performed by McCoy, Waack and Foreman at St. Edward and by McCoy at Sparks have been furnished to Medicare, Medicaid, TRICARE, Federal Employees Health Benefits Program, Railroad Retirement and other federal health care program beneficiaries. Services provided for these federal health care program beneficiaries have been paid for in whole or in part by the United States.

32. McCoy also has received substantial payments from federal health care programs on claims he submitted for medical consultation services.

33. Defendants have knowingly defrauded the United States in one or more of the following respects:

- (a) From 1994, or earlier, until at least May, 2000, McCoy, Waack, and Foreman knowingly and systematically billed to and collected from Medicare and other government health care programs **false claims for payment of medically unnecessary surgical and interventional procedures** performed at St. Edward, with the knowledge and complicity, and in part for the benefit, of Cooper;
- (b) Since at least 1994, St. Edward has knowingly and systematically billed to and collected from Medicare and other government health care programs **false claims for payment of hospital patient services and facilities related to the medically unnecessary surgical and interventional procedures**, with the knowledge and complicity, and in part for the benefit, of

Mercy System;

(c) Since 2001, McCoy has knowingly and systematically billed to and collected from Medicare and other government health care programs **false claims for payment of medically unnecessary surgical and interventional procedures** performed at Sparks, with the knowledge and complicity, and in part for the benefit, of Western Associates;

(d) Since 2001, Sparks has knowingly and systematically billed to and collected from Medicare and other government health care programs **false claims for payment of hospital patient services and facilities related to the medically unnecessary surgical and interventional procedures** performed by McCoy, with the knowledge and complicity, and in part for the benefit, of Sparks System; and

(e) Since at least 1994, McCoy has knowingly and systematically billed to and collected from Medicare and other government health care programs **false claims for payment of medical consultation services that were not performed.**

34. In furtherance of their fraudulent schemes and in support of their false claims submitted to federal health care programs, Defendants have knowingly made and used false records and statements to get claims paid, including, but not limited to, the following representative examples:

(a) Cooper Clinic physicians McCoy, Waack and Foreman falsified patient records to make it appear that surgical and interventional procedures were medically indicated and necessary, when in fact the services were unsupported by indicated criteria and medically unnecessary;

(b) St. Edward, Cooper Clinic and Cooper Clinic physicians fraudulently manipulated the adverse patient outcome information presented to oversight committees and oversight organizations in order to conceal and obscure mortalities and morbidities resulting from unnecessary procedures;

(c) McCoy falsified patient records to make it appear that he performed consultation services he in fact did not perform.

35. Through their submission of false claims and creation and use of false records and statements to get those claims paid by the United States, Defendants have fraudulently inflated the payments and reimbursements claimed and received from federal health care programs.

36. This complaint identifies certain false claims presented and false records and statements made or used by the Defendants in furtherance of their fraudulent schemes and sets forth the basic

framework, procedures, and the nature of the fraudulent schemes. Discovery will be necessary to identify each false claim, record, and statement for the following reasons:

- (a) this case involves sophisticated schemes to defraud that were perpetrated by numerous individuals, corporations, and related business entities;
- (b) the false claims presented, and the false records and statements made, used, or caused to be made or used by Defendants in furtherance of their schemes are numerous and were presented over an extended period of time; and
- (b) documents evidencing many of the false claims, records and statements are peculiarly within the possession of Defendants.¹

VIII.

The Defendants' fraudulent conduct

A. False claims for medically unnecessary cardiac and vascular surgical and interventional procedures performed by McCoy, Waack and Foreman at St. Edward and related St. Edward hospital charges

37. From 1994, or earlier, until at least May, 2000, Cooper Clinic member physicians McCoy, Waack and Foreman knowingly, systematically, routinely and repeatedly submitted false claims to and received reimbursements from Medicare and other federal health care programs for medically unnecessary cardiac and vascular surgical and interventional procedures, including, but not limited to, coronary bypass grafting, lower extremity bypass grafting, and carotid artery bypass grafting. As a result of these false claims, Cooper Clinic, McCoy, Waack and Foreman fraudulently obtained

¹ While some documentary evidence of the false claims, records and statements are within the possession of third parties such as the Centers for Medicare and Medicaid Services (CMS), Plaintiffs are legally prohibited from obtaining such records. See 45 C.F.R. §5.67 (The Department of Health and Human Services will not disclose names and addresses of individual beneficiaries of its programs, or benefits such individuals receive; or claim files maintained by the Social Security Administration, the Public Health Service, and the CMS).

payments from Medicare and other federal health care programs to which they were not entitled.

38. From at least 1994, St. Edward knowingly, systematically, routinely and repeatedly submitted false claims to and received reimbursements from Medicare and other federal health care programs for hospital services, items and facilities furnished in connection with the medically unnecessary cardiac and vascular surgical and interventional procedures performed by Cooper Clinic member physicians McCoy, Waack and Foreman at its facilities. As a result of these false claims, St Edward and its parent corporation Mercy System fraudulently obtained payments from Medicare and other federal health care programs to which they were not entitled.

1. Increased patient risks resulting from medically unnecessary cardiac and vascular procedures

39. Bypassing an otherwise normal coronary artery predisposes the patient to early closure of the patient's heart vessels, heart attack and death.

40. Similarly, medically unnecessary lower extremity vascular bypass grafts place the patient at increased risk for interrupting normal blood flow, which predisposes the patient to limb loss.

2. Scheme for filing false claims for medically unnecessary cardiac and vascular surgical and interventional procedures

41. In an effort to establish and promote the rapid development of a competitive cardiovascular surgery program at St. Edward, and increase revenues for St. Edward, Cooper Clinic, and Cooper Clinic's physicians, McCoy, Waack and Foreman, with the knowledge, cooperation and support of St. Edward, engaged in a practice pattern of performing medically unnecessary cardiac and vascular surgical and interventional procedures.

42. St. Edward recruited McCoy in approximately 1993 for the specific purpose of developing the cardiovascular surgery program at St. Edward.

43. In 1999, during McCoy's tenure at St. Edward, St. Edward's previously undistinguished

cardiovascular program was recognized as one of the top 100 heart hospitals in the United States by Solucient.² Conversely, St. Edward's cardiovascular program quickly downsized after McCoy left in May, 2000.

44. St. Edward's recognition in 1999 as a top heart hospital, however, was accomplished through improper practices and at the expense of patients' health and safety. Specifically McCoy, Waack, Foreman, and possibly other Cooper Clinic physicians, performed medically unnecessary surgical and interventional procedures that resulted in higher mortality and morbidity rates and predisposed patients to increased health risks, including death. Harrison is not aware of a single instance where he referred a patient to McCoy that McCoy did not recommend surgery. A number of times after Harrison evaluated a patient and in his opinion determined that surgery was unnecessary, without first conferring with Harrison, McCoy approached Harrison's patient and strongly recommended surgery.

45. Harrison served as a member of the CABG/Specials committee at St. Edward, a peer review committee that reviewed medical necessity, quality of care and other issues concerning cardiac surgery and angioplasty. Waack, while serving as chair of the CABG/Specials committee, approached Harrison, reproached him for performing too many angioplasties, and told Harrison that

² Solucient describes itself as a source of health care business intelligence to providers, payers, employers and pharmaceutical companies. Starting in 1993, Solucient has published various types of annual 100 Top Hospitals studies. The objective of Solucient's 100 Top Hospital program is to annually identify hospitals that have achieved an overall top performance based upon empirical findings from publically available performance data. Solucient has published an annual cardiovascular study since 1999. The winners of the annual cardiovascular award are stratified in categories or peer groups that represent hospitals throughout the country. They include 30 teaching hospitals with cardiovascular residency programs, 40 teaching hospitals without cardiovascular residency programs and 30 community hospitals.

McCoy needed more patients for surgery and that Harrison should choose surgery more often and send McCoy more patients.

46. Over time, Harrison and other independent, physician committee members (non-Cooper Clinic physicians) realized that many known adverse patient outcomes of Cooper Clinic physicians went unreported, were incorrectly reported, or were concealed or obscured, and were not presented to the peer review committee. This allowed Cooper physicians such as McCoy, Waack and Foreman to perform their procedures with very little or nonexistent oversight. One example is a known patient fatality resulting from a routine angioplasty performed by Waack that was never presented to the committee. Another example is Foreman's known placement of a coronary stent in a patient's normal (i.e. undiseased) coronary artery which never reached committee.

47. McCoy, in particular, experienced unusually high mortality and morbidity rates of eight to ten percent for coronary artery bypass surgery. The average statistical mortality and morbidity rate for surgeons performing the same types of procedures as McCoy is normally less than two percent. Nonetheless, McCoy's cases involving complications or fatalities rarely came before the peer review committee. Even when one of McCoy's cases came before the committee, the only other vascular surgeons on the committee were surgeons from Sparks that never attended committee meetings. This provided McCoy with essentially no supervision or accountability for his work.

48. St. Edward, Cooper Clinic and certain Cooper Clinic physicians acted in concert to cover up McCoy's abnormally high mortality and morbidity rates. On at least one occasion, St. Edward instructed one of its employees to mask McCoy's abnormal mortality and morbidity rates. One way this was accomplished was by aggregating McCoy's mortalities and morbidities and the mortalities and morbidities of all surgeons of all practice groups and reporting averaged numbers to peer review and hospital certification groups, including the Joint Commission on the Accreditation of Healthcare

Organizations (JCAHO) and the Arkansas Health Department. This was done by St. Edward to maintain its Medicare certification and avoid jeopardizing its cardiovascular program. Another way was to deliberately bombard oversight committees and agencies with voluminous information to obfuscate the abnormal statistics.

49. In short, Defendants at the expense of their patients' welfare engaged in unlawful conduct to enhance their prestige and make more money.

3. Specific examples of defendants' false claims for medically unnecessary cardiac and vascular surgical and interventional procedures

50. Specific examples of Defendants' false claims for medically unnecessary cardiac and vascular surgical procedures include the following incidents:

a. Relator Paul Montgomery

i. Unnecessary coronary bypass surgery

51. McCoy performed medically unnecessary coronary bypass surgery on Montgomery based on a left main coronary artery lesion (blockage) that McCoy knew did not exist.

52. In 1996, Montgomery experienced chest pain, presented to his local physician and was referred to Sparks for a cardiac catheterization (also referred to as an angiogram or arteriogram). A cardiac catheterization is an injection of contrast directly into the heart vessels through a diagnostic catheter placed into a leg or arm artery. An x-ray is taken of the contrast moving through the arteries. Blockages and narrowings of the vessels can be detected from the x-ray. This is the definitive study for determining blockages in the heart vessels.

53. The arteriogram revealed a totally occluded (blocked) right coronary artery representing an old heart attack. Montgomery's cardiologist determined he did not need surgery and Montgomery was treated medically.

54. In June of 1998, Montgomery was referred to McCoy for evaluation with complaints of vague left ankle pain on long walks.

55. McCoy examined Montgomery and falsely wrote in Montgomery's chart that the patient had pain in his calves when walking short distances that interfered with his lifestyle and that he could only walk on a home tread mill less than three minutes, a description which Montgomery disputes as an outright fabrication. 56. In contrast to McCoy's characterization of Montgomery's condition, at the time of his examination and until days before the surgeries described below, Montgomery engaged in long periods of daily, strenuous physical labor. In early 1998 Montgomery had accepted a contracting job with the Fort Smith Historical District to rebuild a house that had been severely damaged by fire. Montgomery's daily routine included the manipulation of heavy equipment and the transport and use of building materials on ladders and scaffolding. During this time, he also engaged in long periods of walking and dancing that caused him no leg or chest pain.

57. McCoy referred Montgomery for two procedures: a nuclear treadmill stress test for his heart, since he had a history of coronary artery disease, and an x-ray contrast study of his legs (See section VIII.A.3.a.ii. below, beginning at ¶ 71).

58. On June 25, 1998, Waack performed a cardiac nuclear stress test on Montgomery. A nuclear stress test involves the injection of a radioisotope into the bloodstream of the patient before and during peak exercise on a treadmill or before and after administering a chemical agent (Persantine) used to simulate exercise. Nuclear images taken of the heart are compared pre-exercise and post-exercise for wall motion abnormalities and coupled with electrocardiogram (ECG), functional, and clinical information.

59. Following the injection of Persantine, Montgomery walked on a treadmill without claudication (leg pain which typically derives from inadequate blood flow in the legs during walking)

until he was instructed to stop after 9 minutes, 43 seconds. Although the nuclear stress test was for Montgomery's heart, it also demonstrated that he could walk long distances without leg pain. Dr. Waack wrote in Montgomery's chart that he complained of "nausea or chest pain" (nausea is the most common side effect of a Persantine injection). However, Montgomery denies making either complaint.

60. The nuclear stress test results revealed a minor abnormality in blood flow to the back of the heart only during exercise. This would suggest the need for cardiac catheterization to determine whether surgery or intervention was necessary. Dr. Waack appropriately scheduled a catheterization for Montgomery.

61. On June 29, 1998, Foreman performed a heart catheterization and a coronary pressure test on Montgomery.

62. Foreman documented a total occluded right coronary artery and a 50% to 70% blockage of the left main coronary artery by angiography.

63. Foreman's interpretation of the angiogram was blatantly inaccurate and false. More than 20 cardiovascular experts have reviewed the films on Montgomery, and all have concluded that his left main coronary artery was normal.

64. To support the false angiographic findings, Foreman performed a procedure to measure differential coronary artery pressures, improperly using a diagnostic catheter instead of a smaller diameter flow wire or pressure wire.

65. Using a diagnostic catheter for this procedure is unconventional and potentially lethal to the patient. The placement of a diagnostic catheter deep into a coronary artery for the measurement of pressures is not taught in any cardiology training program, and in fact is contraindicated. It is potentially lethal because the diagnostic catheter is stiff and can dislodge plaque causing a heart

attack.

66. Furthermore, the pressure readings are always false when, as in Montgomery's case, the diagnostic catheter is nearly the same size as the coronary artery. Under these conditions, the catheter restricts blood flow through the vessel, causing artificially low pressure differential readings.

67. Based on his false angiographic findings and an improperly administered coronary pressure test, Foreman reported that Montgomery suffered from right coronary artery total occlusion (totally blocked) and left main coronary artery disease causing a stenosis (narrowing) of fifty to seventy percent.

68. McCoy informed Montgomery that if he did not have coronary artery bypass surgery quickly he could die. McCoy strongly discouraged Montgomery's requests for a second opinion, stating that Montgomery would risk dying before a second opinion could be obtained.

69. On June 30, 1998, Defendant McCoy performed quadruple coronary artery bypass surgery on Montgomery.

70. The surgery was medically unnecessary, as the left main coronary artery was normal. In 2002, Montgomery underwent a third heart study performed by another physician. The 1996, 1998 and 2002 heart studies have been reviewed and evaluated by more than 20 cardiovascular surgeons and cardiologists who have all reached the same conclusion that there was no left main disease, blockage or narrowing.

ii. Unnecessary aorta-bifemoral angiogram and lower extremity bypass surgery

71. In August, 1998 McCoy performed medically unnecessary bypass surgery (femoral-popliteal bypass surgery) on relator Montgomery's legs in total disregard of the patient's history and without performing appropriate preliminary non-invasive testing. Complications arising from this unnecessary, initial surgery precipitated the need for several additional surgeries and directly resulted

in the eventual above-the-knee amputation of Montgomery's right leg.

72. There are only two surgical indications for femoral-popliteal bypass surgery. The first indication is to salvage a dying and ischemic (lack of blood flow) lower extremity. The second indication is life-style altering claudication (intermittent cramping pain in the lower extremities on ambulation that is reproducible at the same level of exertion) when walking long distances.

73. As stated in paragraphs 54-56 above, in June of 1998 when Montgomery was referred to McCoy for evaluation with complaints of a vague left ankle pain on long walks, McCoy falsely documented in Montgomery's chart that Montgomery had pain in his calves when walking short distances that interfered with his lifestyle and recommended surgery.

74. On June 29, 1998, an aorta-bifemoral angiogram was performed on Montgomery's legs at St. Edward's radiology department. An aorta-bifemoral angiogram is the injection of a radio-opaque contrast material into the blood stream that is then tracked as it flows into the lower extremities in order to assess flow and possible blockages.

75. An angiogram clearly was not indicated. An angiogram is indicated only when the patient's history supports life altering claudication or a dying lower extremity. Claudication must be documented by both patient history and non-invasive studies, such as an ankle/brachial indices, doppler studies or ultrasound studies.

76. Montgomery had no history of claudication. As mentioned in paragraph 59 above, he walked on a treadmill without claudication for 9 minutes, 43 seconds, demonstrating that he could walk long distances without leg pain. Also as mentioned above, only days before his surgery Montgomery was restoring a Victorian house, climbing ladders and scaffolding without claudication, and he also ran a foot race with Arkansas Southside football coach Lunney without leg pain. Only two days before his leg surgery he danced virtually non-stop for four and a half hours at his class reunion, as witnessed by

many.

77. Furthermore, none of the referenced non-invasive procedures were performed to determine the existence or non-existence of claudication. By neglecting to perform any non-invasive intermediate procedures, McCoy and St. Edward avoided creating a record that would have documented the lack of medical necessity for the femoral-popliteal bypass.

78. On August 25, 1998, Defendant McCoy performed bilateral femoral-popliteal bypass surgery on Montgomery. This surgical procedure uses artificial or vein grafts to bypass diseased sections of blood vessels in the leg. It is an invasive procedure that is usually performed only in the event of threatened limb loss (cold, ischemic leg) or lifestyle-limiting claudication, neither of which Montgomery demonstrated. This surgery was not only medically unnecessary, it was contraindicated by the actual available data.

79. If, as in this case, bypass grafts are placed needlessly, the patient is then placed at increased risk for interruption of normal blood flow, which predisposes the patient to limb loss.

80. As a direct result of complications arising from the initial, medically unnecessary leg bypass surgery, Montgomery underwent five subsequent surgeries, including the eventual above-the-knee amputation of his right leg. Including the unnecessary coronary bypass, lower extremity bypass and angiogram procedures, Montgomery underwent seven surgeries and one interventional procedure that he would not have suffered, but for the fraudulent conduct of McCoy and the other Cooper Clinic physicians.

b. Beneficiary DU

81. Defendant McCoy performed medically unnecessary cardiac bypass surgery on DU, bypassing an otherwise normal coronary vessel with minimal disease that had been previously diagnosed as having coronary spasm.

82. Bypass surgery is never indicated for a diagnosis of coronary artery spasm. In fact, it is a contraindication to bypass a vessel for coronary artery spasm because it predisposes the patient to early closure of the patient's heart vessels, heart attack and death.

83. In May of 2000, DU underwent heart catheterization (performed by an independent cardiologist at St. Edward) to evaluate chest pain she had experienced for approximately twenty years. The results showed mild disease in the left anterior descending coronary artery and significant transient (intermittent) narrowing which the cardiologist thought might be due to coronary artery spasm. Coronary artery spasm is transient muscle spasm that narrows the vessel diameter, decreasing blood flow and causing chest pain. It is common for the dye or the catheter to stimulate coronary spasm when a heart catheterization is performed. Consistent with the standard of care, the cardiologist appropriately injected intracoronary nitroglycerin. The spasm was promptly relieved and the vessel returned to its pre-spasm state.

84. This heart catheterization confirmed the diagnosis of coronary artery spasm and the lack of need for surgery. DU was placed on anti-spasm medication and sent home.

85. In June 2000, DU underwent a second heart catheterization, because the anti-spasm medication had not relieved her recurring chest pain. The results were the same. However, this time DU was not given intracoronary injection of nitroglycerin in order to substantiate the prior diagnosis of coronary artery spasm. Instead, DU was referred to Dr. McCoy for evaluation.

86. Within days of the second catheterization, McCoy performed unnecessary coronary artery bypass surgery on DU.

87. This procedure was medically unnecessary because coronary artery spasm is always treated medically, never surgically. The procedure was also contraindicated because it predisposed the patient to further risks.

88. Some months later, DU was evaluated by Harrison for recurring chest pain. Harrison reviewed DU's angiograms and other medical records and concluded that DU was bypassed needlessly. She was subsequently treated aggressively with medications for coronary artery spasm and in time improved.

c. Beneficiary VM

89. Defendant Foreman performed medically unnecessary coronary angioplasty and stenting of a normal right coronary artery on patient VM.

90. In 1997, Harrison, Waack and another cardiologist, Dr. Andre Nolewajka, witnessed Foreman perform a catheterizaion on VM, the results of which showed that VM had normal coronary arteries and coronary spasm. The standard of care would have been to end the procedure without further intervention.

91. Foreman nevertheless performed a balloon angioplasty and stented VM's normal right coronary artery. Balloon angioplasty is the insertion into the coronary artery of a balloon device, which is expanded to open a narrowed or blocked vessel. Insertion of a stent then follows balloon angioplasty. It is a metal spring device that is expanded to hold the vessel walls open.

92. As Foreman was performing the angioplasty, Waack commented in the presence and hearing of Harrison and Nolewajka that VM's coronary artery was normal. Waack then walked from the viewing room into the catheterization suite and stated to Foreman that he had "just stented a normal coronary artery." Harrison and Nolewajka overheard this statement.

93. Harrison later learned that VM had been placed on ulcer medication for his chest pain and discharged from the hospital.

94. The coronary stent procedure was medically unnecessary and predisposes VM to early closure of the coronary vessel, heart attack and death..

B. McCoy's false claims based on his placement of extra, medically unnecessary bypass grafts on normal vessels, in connection with his performance of medically necessary bypass surgeries on diseased vessels

95. From 1997, or earlier, until at least 1999, Cooper Clinic physician McCoy knowingly, systematically, routinely and repeatedly submitted false claims to and received reimbursements from Medicare and other federal health care programs for medically unnecessary bypass grafts performed as part of otherwise medically necessary surgeries. As a result of these false claims, Cooper Clinic and McCoy fraudulently obtained payments from Medicare and other federal health care programs to which they were not entitled.

1. Coding and billing of coronary artery bypass procedures

96. Physician claims for coronary artery bypass procedures are reported and billed to Medicare, and other federal health care programs and commercial insurers, using the HCFA Common Procedure Coding System (HCPCS) Level I, CPT codes and modifiers designated by the Centers for Medicare & Medicaid Services (CMS), formerly known as the Health Care Financing Administration (HCFA) (HCFA was renamed the Centers for Medicare & Medicaid Services on June 14, 2001).³

97. The coronary artery bypass CPT codes are organized under three subheadings (i) venous

³ Developed by HCFA in 1983, the HCPCS is a uniform method for reporting physician and other health care professional and medical supplier services, procedures, and supplies. The three levels of HCPCS codes are as follows:

- Level I: CPT. The Physicians' Current Procedural Terminology ("CPT") is published annually by the American Medical Association and is a systematic listing and coding of contemporary procedures and services performed by physicians in clinical practice in the United States. It provides a uniform language to concisely and accurately describe medical, surgical and diagnostic procedures and thereby simplify the reporting of services. Under this system, each service and procedure is identified by a descriptor (a verbal expression of the name of the service or procedure) and its specifically assigned five-digit code number. CMS has adopted the CPT terminology and coding system.
- Level II: HCPCS National Codes. Created and updated annually by CMS for services not included in CPT codes.
- Level III: Local Codes. Created and maintained by individual state Medicare carriers for services not included in the Level I or Level II codes.

grafting only for coronary bypass, (ii) combined arterial-venous grafting for coronary bypass (procedures using venous grafts and arterial grafts during the same procedure) and (iii) arterial grafting for coronary bypass.

98. To report combined arterial-venous grafts it is necessary to report two codes: 1) the appropriate combined arterial-venous graft code (CPT codes 33517 - 33523, *See ¶ 99 below*); and 2) the appropriate arterial graft code (CPT codes 33533 - 33536, *See ¶ 99 below*).

99. The CPT codes used to report physician coronary artery bypass procedures to Medicare and the approximate amounts payable by Medicare for such procedures are as follows:

Grafts	Venous Grafting	Combined Arterial-Venous Grafting	Arterial Grafting
single graft	33510 \$1,710.51	33517 \$159.66	33533 \$1,755.57
two grafts	33511 \$1,850.69	33518 \$301.24	33534 \$1,930.81
three grafts	33512 \$1,987.76	33519 \$442.01	33535 \$2,111.27
four grafts	33513 \$2,133.40	33521 \$583.45	33536 \$2,288.59 (four or more grafts)
five grafts	33514 \$2,326.19	33522 \$724.39	
six or more grafts	33516 \$2,476.82	33523 \$866.45	

100. As the table illustrates, the greater the number of grafts, the greater the amount paid by Medicare and other federal healthcare programs.

2. McCoy's fraudulent placement of grafts on normal vessels, in connection with his placement of medically necessary grafts on diseased vessels

101. From approximately 1997 to 1999, Harrison re-reviewed heart catheterization studies on a

number his patients who proceeded to surgery for a discrete number of bypass grafts only to return from surgery with needless, additional grafts on normal coronary arteries.

102. By way of example, Harrison's patient John Doe was referred to McCoy for two-vessel coronary artery bypass surgery. Post-operatively, Harrison noted that five vessels were bypassed. Harrison re-reviewed the original heart catheterization and discovered that McCoy bypassed three coronary arteries needlessly.

103. The example of John Doe is not unique. Harrison personally reviewed films at St. Edwards of no fewer than seven similar instances.

104. Harrison asked McCoy why he placed bypass grafts to normal heart vessels, and McCoy's response was that this practice was "precautionary." Harrison asked McCoy if he could provide relevant medical literature to support his practice of bypassing normal vessels. McCoy's response was that he did not know of any literature.

105. Harrison began sending his patients for bypass surgeries to other cardiovascular surgeons out of his concern regarding McCoy's practice pattern of bypassing normal vessels. As noted above, bypass grafts placed on normal vessels predisposed the patient to early closure of that vessel, heart attack and death.

106. St. Edward's CEO Mike Morgan confronted Harrison and stated he would not allow any of Harrison's patients to be transferred from St. Edward unless approved by McCoy.

107. Morgan additionally issued standing orders at St. Edward that if Harrison initiated the transfer of a patient to another facility, Morgan was to be notified at home. In one instance, Harrison was transferring a patient to another cardiovascular surgeon at Sparks and the transfer was halted by St. Edward security pursuant to Morgan's orders. Morgan threatened Harrison that if he pursued these practices, his privileges at St. Edward would be suspended.

C. False claims for medically unnecessary cardiac and vascular surgical and interventional procedures performed by McCoy at Sparks and related Sparks hospital charges

108. Since 2001, Western Associates member physician McCoy has knowingly, systematically, routinely and repeatedly submitted false claims to and received reimbursements from Medicare and other federal health care programs for medically unnecessary cardiac and vascular surgical and interventional procedures, including, but not limited to, coronary bypass grafting, lower extremity bypass grafting and carotid artery bypass grafting. As a result of these false claims, Western Associates and McCoy have fraudulently obtained payments from Medicare and other federal health care programs to which they were not entitled.

109. Since 2001, Sparks has knowingly, systematically, routinely and repeatedly submitted false claims to and received reimbursements from Medicare and other federal health care programs for hospital services, items and facilities furnished in connection with the medically unnecessary cardiac and vascular surgical and interventional procedures performed by Western Associates member physician McCoy at its facilities. As a result of these false claims, Sparks and its parent corporation Sparks System have fraudulently obtained payments from Medicare and other federal health care programs to which they were not entitled.

110. In 2001, McCoy joined Western Associates and began performing his surgeries at Sparks.

111. Since that time, McCoy has engaged in the same pattern of practice that he engaged in at St Edward, performing medically unnecessary surgeries. Spark's marketing materials boast that McCoy and another Western Associates' physician together performed 519 heart bypass procedures in a year and accounted for 60% of all heart bypass surgeries in Fort Smith. However, the demographics of the relevant patient population served do not support the number of bypass surgeries performed by

McCoy at Sparks.⁴ Instead, the number of surgeries, in part, is a function of McCoy's performance of unnecessary procedures.

D. McCoy knowingly submitted false claims to Medicare and other federal health care programs for medical consultation services that were not performed

112. From at least 1995 to 2000, McCoy has knowingly, systematically, routinely and repeatedly submitted false claims to and received reimbursements from Medicare and other federal health care programs for medical consultation services that were not performed. As a result of these false claims, McCoy fraudulently obtained payments from Medicare and other federal health care programs to which he was not entitled.

1. Consultation services

113. A consultation is a type of service provided by a physician whose opinion or advice regarding evaluation and /or management of a specific problem is requested by another physician or other appropriate source.

114. The request for a consultation from the attending physician or other appropriate source and the need for consultation must be documented in the patient's medical record. The consultant's opinion and any services that were ordered or performed must also be documented in the patient's medical record and communicated to the requesting physician or other appropriate source.

115. There are four subcategories of consultations: office and other outpatient, initial inpatient, follow-up inpatient, and confirmatory.

⁴ As of the 2000 census, Fort Smith had a total population of 80,268.. The Fort Smith Metropolitan Statistical Area (Crawford, Franklin and Sebastian Counties in Arkansas and Leflore and Sequoyah Counties in Oklahoma) has a population of approximately 273,000.

116. The HCPCS Level I, CPT codes (*See* ¶ 96 and n. 3 above) used to report and bill consultations services to Medicare⁵ and the approximate amounts payable by Medicare for such services are as follows:

Office or Other Outpatient	Initial Inpatient	Follow-up Inpatient	Confirmatory
99241 \$49.22	99251 \$39.58	99261 \$23.72	99271 \$35.09
99241 \$32.00 (Facility Setting) ⁶			99271 \$24.14 (Facility Setting)
99242 \$81.57	99252 \$68.84	99262 \$43.56	99272 \$54.47
99242 \$60.28 (Facility Setting)			99272 \$41.94 (Facility Setting)
99243 \$104.54	99253 \$92.69	99263 \$64.46	99273 \$76.05
99243 \$79.81 (Facility Setting)			99273 \$59.15 (Facility Setting)
99244 \$145.80	99254 \$130.37		99274 \$103.33
99244 \$116.69 (Facility Setting)			99274 \$83.29 (Facility Setting)
99245	99255		99275

⁵ 2000 Arkansas fee schedule

⁶ Payments to physicians reflect the relative differences in operating expenses realized by physicians in different practice settings. In this regard, physician reimbursement is generally based on the costs associated with performing the service. This cost is designed to compensate physicians for the work required to perform the service, the overhead required to provide the service and the malpractice expense attributable to the service. Accordingly, physician services of the type ordinarily furnished in physicians' offices, that are provided in a facility setting, such as a hospital, are reimbursed at a lower rate than the same service provided in a private physician office.

Office or Other Outpatient	Initial Inpatient	Follow-up Inpatient	Confirmatory
\$189.68	\$178.09		\$135.92
99245 \$155.56 (Facility Setting)			99275 \$125.59 (Facility Setting)

2. McCoy's scheme for filing false claims for medical consultation services that were not performed

117. From at least 1995 to 2000, McCoy billed and received payments from Medicare and other federal health care programs for consultations fraudulently and falsely claimed to have been performed for patients of Harrison and other cardiologists who underwent angioplasty, when in fact there was no request by the attending physician for a consult and McCoy did not see the patient or perform a consult.

118. During that time, it was a standard procedure for McCoy or his nurse to call the catheterization suite at St. Edward each day to obtain the name and insurance information of every patient scheduled for angioplasty.

119. McCoy would use that information to bill consultations for scheduled angioplasty patients, including beneficiaries of Medicare and other federal health care programs. Harrison noted that McCoy occasionally would document in the chart "angioplasty standby performed."

120. The alleged consultations were not requested by the patients' attending physicians. McCoy did not see the patients and did not perform any consultation services. St. Edward had knowledge of and encouraged this practice by McCoy.

121. As a result of this fraudulent practice pattern, McCoy received tens of thousands of dollars from Medicare and other federal programs for services he did not perform.

IX.

The United States has been damaged

122. As more particularly described above, Defendants have profited and the United States has been damaged monetarily by the practices used by Defendants to make false claims to federal health care programs for payment and reimbursement. Defendants have submitted many false claims for excessive and unauthorized payments and reimbursements and have obtained excessive compensation from the United States as a result.

X.

Count One

Federal False Claims Act 31 U.S.C. § 3729(a)(1)

123. Plaintiffs reallege and incorporate by reference the allegations contained in Paragraphs 1 through 122 of this complaint.

124. This is a claim for treble damages, civil penalties and attorney's fees, under the Federal False Claims Act, 31 U.S.C. §§ 3729, *et seq.* as amended.

125. By means of the acts described above, Defendants have knowingly presented or caused to be presented false or fraudulent claims for payment to the United States. The United States, unaware of the falsity of the claims made, and in reliance on the accuracy thereof, paid for claims that would otherwise not have been allowed.

126. By reason of these payments, the United States has been damaged, and continues to be damaged, in a substantial amount.

XI.

Count Two

Federal False Claims Act 31 U.S.C. § 3729(a)(2)

127. Plaintiffs reallege and incorporate by reference the allegations contained in Paragraphs 1 through 122 of this complaint.

128. This is a claim for treble damages, civil penalties and attorney's fees, under the Federal False Claims Act, 31 U.S.C. §§ 3729, *et seq.* as amended.

129. By means of the acts described above, Defendants have knowingly made, used, or caused to be made or used, false records and statements to get false or fraudulent claims paid by the United States. The United States, unaware of the falsity of the records and statements, and in reliance on the accuracy thereof, paid for claims that would otherwise not have been allowed.

130. By reason of these payments, the United States has been damaged, and continues to be damaged, in a substantial amount.

XII.

Count Three

Federal False Claims Act 31 U.S.C. § 3729(a)(3)

131. Plaintiffs reallege and incorporate by reference the allegations contained in Paragraphs 1 through 122 of this complaint.

132. This is a claim for treble damages, civil penalties and attorney's fees, under the Federal False Claims Act, 31 U.S.C. §§ 3729, *et seq.* as amended.

133. By means of the acts described above, Defendants conspired to defraud the United States by getting false or fraudulent claims allowed or paid. The United States, unaware of the conspiracy, and unaware of the falsity of the records, statements and claims made, and in reliance on the accuracy thereof, paid for claims that would otherwise not have been allowed.

134. By reason of these payments, the United States has been damaged, and continues to be damaged, in a substantial amount.

XIII.

Conclusion

135. The defendants are liable to the United States Government for civil penalties and treble damages, pursuant to 31 U.S.C. § 3729(a). In addition, the plaintiffs are entitled to recover reasonable expenses, attorney's fees, and costs incurred in prosecuting this action, pursuant to 31 U.S.C. § 3730(d). Further, the plaintiffs are entitled to a share of the recovery obtained by the United States as a result of this action, pursuant to 31 U.S.C. § 3730 (d).

WHEREFORE, Plaintiffs pray that upon trial or final hearing the Court grant judgment for Plaintiffs and the United States against the Defendants, as follows:

- a. for civil penalties for each false claim pursuant to 31 U.S.C. § 3729(a);
- b. for three times the amount of damages proved, pursuant to 31 U.S.C. § 3729(a);
- c. for reasonable attorneys' fees and expenses;
- d. for costs of court;
- e. for pre-judgment and post-judgment interest at the rates permitted by law; and
- f. for such other and further relief as may be appropriate and authorized by law.

Plaintiffs further pray that he be awarded an appropriate percentage of the amount recovered by and for the United States as a result of this action, in accordance with 31 U.S.C. § 3730(d).

Respectfully submitted,



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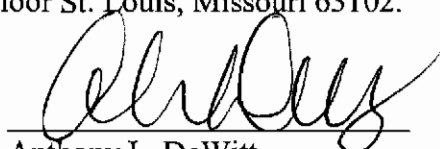
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CERTIFICATE OF SERVICE

I certify that a true and correct copy of the foregoing complaint has been served this 22nd day of April, 2005, by [overnight mail or first class mail] upon the Honorable Albert Gonzales, United States Attorney General, 950 Pennsylvania Ave., NW, Washington, D.C. 20530, and by UPS delivery upon the Honorable James G. Martin, United States Attorney for the Eastern District of Missouri, Thomas F. Eagleton U.S. Courthouse, 111 South 10th Street, 20th Floor St. Louis, Missouri 63102.


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